appendix

Measures for the Supervision and Inspection of Drug Clinical Trial Institutions (Trial Implementation)

Chapter I General Provisions

Article 1 These Measures are formulated in accordance with the Drug Administration Law of the People's Republic of China, the Vaccine Administration Law of the People's Republic of China, the Drug Registration Management Measures, the Drug Clinical Trial Institution Management Regulations, and the Good Clinical Practice for Drug Clinical Trials (hereinafter referred to as GCP) to standardize the supervision and inspection of drug clinical trial institutions and strengthen the management of drug clinical trials. Article 2 These Measures shall apply to the inspection and disposal of drug

supervision and administration departments on the filing of drug clinical trial institutions (hereinafter referred to as trial institutions) and the compliance with relevant laws and regulations and the implementation of GCP in drug clinical trial activities for the purpose of drug registration. Article 3 The State Drug Administration (hereinafter referred to as the State Drug Administration) shall be responsible for formulating

the supervision and inspection system for trial institutions, guiding provincial drug supervision and administration departments (hereinafter referred to as provincial bureaus) to carry out supervision and inspection of trial institutions, and organizing supervision and inspection of trial institutions as needed. The Food and Drug Review and Inspection Center of the State Drug Administration (hereinafter referred to as the State Drug Administration Verification Center) shall be responsible for establishing a national inspector database and implementing inspector training and management, and for implementing the inspection of trial institutions and drug registration verification organized by the State Drug Administration; promoting the informatization of the filing management of trial institutions and the informatization of supervision and inspection work; evaluating the quality management system of provincial drug inspection institutions and providing technical guidance for the inspection work of various provinces.

Article 4 Provincial bureaus are responsible for the supervision and inspection of testing institutions within their administrative areas.

and related matters assigned by the State Administration, establish a supervision and inspection system and mechanism for test institutions, and equip a provincial inspector team that matches the inspection work of the province's test institutions; promote the informatization of supervision and inspection work; organize daily supervision and inspection, cause-based inspections, and other inspections of test institutions within the administrative region, and supervise the test institutions to comply with statutory requirements; and deal with suspected illegal and irregular behaviors of test institutions within the administrative region in accordance with the law.

Article 5 The drug inspection agency set up by the drug supervision and administration department shall conduct inspections of test institutions in accordance with the law, and drug inspection, review and other institutions shall provide technical support according to the needs of the

inspection work of the test institutions. Article 6 The test institutions and researchers shall earnestly perform the relevant responsibilities of drug clinical trials. When authorizing other personnel to undertake relevant work of clinical trials, they shall establish corresponding management procedures, take measures to implement quality management, and strengthen relevant information construction. The researcher shall supervise all authorized personnel to conduct clinical trials in accordance with laws and regulations, implement trial plans, perform work duties, protect the rights and interests and safety of subjects, and ensure that the test data and results are true, accurate, complete and reliable.

Article 7 According to the nature and purpose of the inspection, the inspection of the testing institution is divided into routine supervision inspection, inspection with cause and other inspection.

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(I) Routine supervision and inspection is carried out in accordance with the annual inspection plan to monitor the compliance of the trial institution with relevant laws and regulations, the implementation of GCP, and the rectification of problems found in previous inspections. Routine supervision and inspection should be carried out based on risk and in combination with the clinical trial projects under development by the trial institution. For the first supervision and inspection after filing, the focus should be on verifying the filing conditions of the trial institution or trial specialty.

(II) For-cause inspection is to conduct specific inspections on the testing institutions that may have quality and safety risks.

Targeted inspections are conducted to identify important clues to suspected violations of laws and regulations, such as complaints or reports. For-cause inspections may not notify the inspected organization in advance, but directly enter the inspection site to conduct inspections on possible problems. (III) Other inspections are inspections other than the above two types of

inspections, such as special inspections.

Inspection, supervision and random inspection, etc.

Chapter II Drug Inspection Organizations and Personnel

Article 8 Drug inspection institutions shall establish an inspection quality management system, improve inspection work procedures, clarify inspection standards and principles, and ensure the quality of inspection work; strengthen the management of inspection records and related documents and archives; regularly review and analyze the inspection work and continuously improve the inspection work of test institutions.

Article 9 Drug inspection agencies shall organize and implement inspection tasks in accordance with the inspection plan. The annual plan for routine supervision and inspection of test institutions shall be organized and formulated by provincial bureaus in combination with the specific circumstances of test institutions and test activities within their administrative regions; inspections may select key contents based on risks, focusing on key areas and key links.

If the following circumstances exist in the test institution, test specialty or researcher, they shall be subject to

The following shall be included in the inspection focus or the inspection

frequency shall be increased: (i) There have been serious non-compliance issues

in the past; (ii) The researcher is responsible for many clinical trial projects at the same time and the researcher's management ability is insufficient.

Or the number of researchers is relatively insufficient, which may affect the quality of the trial;

(III) Complaints, reports or other clues indicating the existence of quality and safety risks. Article 10 Inspection personnel shall have

the corresponding inspection qualifications and capabilities; they shall strictly abide by laws and regulations, integrity discipline and work requirements, and shall not make any

Requirements not related to the inspection; they should receive integrity education, sign a letter of commitment and a declaration of no conflict of interest before the inspection; if they have a conflict of interest with the inspected institution or there are other circumstances that may affect the impartiality of the inspection results, they should actively declare and recuse themselves.

Article 11 Inspection personnel shall strictly abide by confidentiality regulations and sign confidentiality agreements, strictly manage confidential information, and strictly prevent leaks. They shall not disclose information related to the inspection and the technology or business secrets of the inspected institution.

Chapter III Inspection Procedure

Article 12 Before implementing the inspection, the drug inspection agency shall formulate a specific inspection plan based on the inspection task, clarifying the inspection content, inspection time and inspection method, etc. The inspection method shall be mainly on-site inspection, and remote inspection may be carried out as appropriate.

Article 13 The drug inspection agency shall form an inspection team to carry out the inspection. The inspection team shall generally consist of two or more inspectors, and the team leader shall be responsible for the inspection. If necessary, experts in relevant fields may be added to participate in the inspection. The inspectors shall be familiar with the inspection plan and relevant inspection materials in advance.

Article 14 After determining the inspection time, the drug inspection agency shall, in principle, notify the inspected institution 5 to 7 working days before the inspection, except for inspections with cause. The inspection of the testing institution implemented by the National Bureau Verification Center shall also notify the provincial bureau where the inspected institution is located. The provincial bureau shall select one drug supervision and management personnel as an observer to assist in the inspection work, and report any problems found during the inspection to the provincial bureau in a timely manner.

Article 15 When the inspection team begins an on-site inspection, it shall hold an initial meeting (except for inspections with cause), show and read the inspection notice to the inspected organization, confirm the scope of the inspection, inform the inspection discipline, anti-corruption discipline, precautions, and the rights and responsibilities of the inspected organization.

The inspected institution shall actively cooperate with

the inspection team, arrange researchers and other relevant personnel familiar with the business to assist the inspection team, provide relevant information in a timely manner, and ensure that the information, data and related circumstances provided are true, accurate, complete and reliable, and shall not refuse, evade, delay or hinder the inspection.

Article 16 The inspection team shall conduct the inspection according to the inspection plan.

If the inspection plan needs to be changed, it should be reported to the inspection dispatching agency for approval before implementation.

Article 17 The inspection team shall record in detail the time, location, content,

existing problems, etc., and retain relevant evidence for the problems found based on the actual situation.

Article 18 The inspection team shall summarize and analyze the on-site inspection results objectively and

Conduct fair and impartial risk assessment and classification of defects discovered during the inspection; if the inspection team assesses that there is a quality and safety risk, it shall require the inspected organization to control the risk in a timely manner and, if necessary, report to the inspection dispatching agency to take further risk control measures.

Article 19 At the end of the on-site inspection, the inspection team shall hold a final meeting to inform the inspected organization of the on-site inspection situation. If the inspected organization has any objection to the on-site inspection situation, it may make a statement of defense. The inspection team shall record it truthfully and determine the defects found in combination with the content of the statement of defense to form a list of defect items. The list of defect items shall be signed and confirmed by the inspection team members, the person in charge of the inspected organization, and the observer (if applicable), and stamped with the official seal of the inspected organization, and each shall keep a copy.

After the inspection team completes the on-site inspection, it shall return all other materials provided by the inspected institution except for the evidence

materials. Article 20 After the on-site inspection is completed, the inspection team shall write an on-site inspection report. List the defects found, their classification, on-site inspection conclusions and treatment suggestions, and

All members of the inspection team shall sign and confirm.

Article 21 Defects found during inspections are classified into serious defects, major defects and general defects. In general, failure of key items to meet requirements is judged as serious defects, failure of major items to meet requirements is judged as major defects, and failure of general items to meet requirements is judged as general defects; the inspection team may classify defects based on the importance, degree of deviation and quality and safety risks of the corresponding inspection points.

Article 22 The inspection team will make a conclusion on the on-site inspection based on the number and risk level of defects found in the test institutions and test disciplines during the inspection, and after comprehensive assessment. The on-site inspection conclusions are divided into compliance with requirements, assessment to be made after rectification, and non-compliance with requirements. If the defects found do not affect the safety of the subjects and/or the quality of the test data or have a slight impact, and the quality management system is considered to be relatively sound, the conclusion is compliance with requirements. If the defects found may affect the safety of the subjects and/or the quality of the test data, but the quality management system is basically sound, the conclusion is assessment to be made after rectification. If the defects found may seriously affect the safety of the subjects and/or the quality of the test data, and it is considered that the quality management system cannot operate effectively or does not meet the basic conditions for the registration of the test institution, the conclusion is non-compliance with requirements.

The inspection team shall make on-site inspection conclusions for the test institution and the test specialty respectively. Article 23 The inspected institution shall rectify the defects found by the inspection team and submit the rectification report to the drug inspection agency within 20 working days after the on-site inspection.

The rectification report shall include the causes of defects, risk assessment, risk control, rectification measures, rectification effect evaluation, etc. For those that cannot be rectified in a short period of time, a feasible rectification plan shall be formulated and included in the rectification report as the rectification status of the corresponding defective items. After the inspected institution completes the rectification according to the rectification plan, it shall promptly submit the rectification status in a supplementary form.

The rectification report shall be submitted to the drug inspection agency.

The inspected institution shall proactively conduct risk assessment based on the defects found and adopt necessary risk control measures. Defects involving test items shall be communicated to the relevant sponsor in a timely manner.

Article 24 The inspection team shall submit the on-site inspection report, on-site inspection record, defect item list and other on-site inspection related materials to the inspection dispatching agency within 5 working days after the on-site inspection is completed.

Article 25 The drug inspection agency shall review the on-site inspection report and other relevant materials of the inspection team within 20 working days, make a comprehensive assessment conclusion and put forward handling opinions to form a comprehensive assessment report. During the review, the defective items and on-site inspection conclusions may be adjusted. If the defective items are adjusted, feedback shall be given to the inspected agency in a timely manner, and the deadline for the inspected agency to submit the rectification report may be extended by 10 working days. The comprehensive assessment conclusion is divided into meeting the requirements and not meeting the requirements. The drug inspection agency shall submit the comprehensive assessment report to the drug supervision and administration department at the same level in a timely manner.

For the evaluation after rectification, the drug inspection agency shall make a comprehensive evaluation conclusion and put forward handling opinions within 20 working days after receiving the rectification report, and submit the comprehensive evaluation report to the drug supervision and administration department at the same level in a timely manner. For those who have not submitted the rectification report, the rectification plan has not been completed, or the rectification is insufficient, and the drug inspection agency assesses that there are certain quality and safety risks, it may propose to the drug supervision and administration department at the same level to suspend new drug clinical trials and other risk control measures, and deal with it after the rectification effect is confirmed.

Article 26 Drug inspection agencies shall establish a communication mechanism. If the comprehensive assessment conclusion is that the drug does not meet the requirements and measures such as suspending new drug clinical trials need to be taken, they shall communicate with the testing institutions as needed. If the testing institutions have objections, they may

To illustrate.

Article 27 If the National Bureau conducts an inspection on a test institution of a verification center and the comprehensive assessment conclusion is that it does not meet the requirements or proposes measures such as suspending new drug clinical trials, the National Bureau will notify the relevant provincial bureaus of the comprehensive assessment conclusion and handling opinions.

The comprehensive assessment conclusion of the test organization is that it does not meet the requirements or takes the suspension For new measures such as clinical trials of drugs (including those notified by the national bureau to the provincial bureau), the provincial bureau shall promptly notify the inspected institution in writing of the comprehensive assessment conclusions and handling opinions, handle them in accordance with the law and take corresponding measures to strengthen

supervision. Article 28 After the inspection task is completed, the drug inspection agency shall promptly organize and archive the on-site inspection records, inspection reports, rectification reports and related evidence materials.

Chapter 4: Checking the connection between relevant work

Article 29 If any suspected illegal acts are found by the testing institution, researcher, etc. during the on-site inspection, the inspection team shall record the inspection situation and the problems found in detail, and adopt various methods such as collecting or copying relevant documents and materials, photographing relevant facilities, equipment and materials and on-site conditions, collecting physical or electronic evidence, and questioning relevant personnel and forming questioning records, etc. according to the actual situation, to promptly fix the evidentiary materials.

Article 30 If the inspection team finds that the testing institution, researcher, etc. are suspected of illegal behavior, it shall immediately report to the provincial bureau and inspection dispatch agency responsible for the daily supervision of the inspected institution. The relevant provincial bureau shall dispatch case investigation personnel to the scene, hand over the evidence materials related to the illegal behavior, and conduct investigation and punishment of the illegal behavior; for those that need to be inspected, they shall organize supervision and random inspection, and send samples and related materials to the relevant drug inspection agency

If the relevant issues may cause safety risks, the provincial bureau shall also order the relevant testing institutions to take risk control measures in a timely manner.

Article 31 If the inspection team finds that the sponsor, biological sample testing unit, etc. are suspected of having serious quality problems during the inspection of the test institution, the inspection team shall report to the inspection dispatching agency, and the inspection dispatching agency shall organize the inspection in a timely manner. If it is necessary to go to other provinces and cities for investigation and evidence collection, it may be carried out jointly with the relevant provincial bureaus, or a letter of assistance in investigation may be issued to request the relevant provincial bureaus to assist in the investigation and evidence collection.

Article 32 If the provincial bureau discovers systemic or regional risks and other widespread and serious illegal acts during the investigation of the test institution, it shall report to the national bureau and put forward handling opinions. The national bureau shall directly organize the investigation, supervise or coordinate the relevant provincial bureaus to file a case for investigation. Article 33 If the inspected unit is found to be suspected of committing a crime during the investigation,

The drug supervision and administration department shall transfer the case to the public security organ in accordance with relevant regulations.

Chapter V Handling of Inspection Results Article 34 For

testing institutions or testing specialties whose comprehensive assessment conclusion is “in compliance with requirements”, the testing institutions shall correct their existing defects on their own and take preventive measures, and the provincial bureaus shall include them in routine supervision.

Article 35: For any testing institution or testing specialty whose comprehensive assessment conclusion is “not meeting the requirements”, the drug supervision and administration department shall require it to suspend new drug clinical trials.

For those who fail to comply with GCP, the drug supervision and administration department shall

It shall be handled in accordance with Article 126 of the National Drug Administration Law and other relevant provisions.

For those who do not comply with GCP or are not suitable to continue to undertake drug clinical trials, Cancel the registration of its drug clinical trial institutions or related trial professionals.

Article 36 If a testing institution or testing specialty is required by the drug supervision and administration department to suspend new drug clinical trials, the testing institution and researchers shall proactively conduct a comprehensive assessment of the drug clinical trials that have already been conducted and take measures to protect the rights and safety of the subjects, and may only enroll subjects after ensuring compliance and controllable risks.

A trial institution or trial specialty whose registration has been cancelled shall not conduct new drug clinical trials from the date of being marked as having its registration cancelled, and shall not enroll subjects in drug clinical trials that have already been conducted. The trial institution and researchers shall safeguard the rights and safety of subjects already enrolled in clinical trials.

Article 37 In principle, the trial institution or trial specialty whose clinical trial is suspended shall complete rectification within 6 months and report the rectification to the provincial bureau where it is located. The provincial bureau shall organize a review of the rectification within 20 working days, and may organize on-site verification or require the trial institution to submit additional rectification materials as needed. The relevant time shall not be included in the working time limit. After the rectification meets the requirements, the trial institution or trial

specialty may conduct new drug clinical trials. If the rectification is not completed within 6 months, or the rectification still does not meet the requirements, its filing will be cancelled.

Article 38 Based on the defects found during the inspection of the test institution, the drug supervision and administration department may take measures such as warnings and interviews to urge the test institution to strengthen quality management.

Article 39 If the researchers and other relevant responsible persons, ethics committees, etc. of the test institution are found to be suspected of violating relevant laws and regulations, the provincial bureau shall notify the relevant competent authorities to handle according to law.

Article 40 The drug supervision and administration department shall, in accordance with relevant regulations, promptly disclose to the public the results of supervision and inspection of trial institutions, investigation and handling of illegal acts, etc. through the "Drug Clinical Trial Institution Registration Management Information Platform". Relevant situations shall be promptly reported to the health and health administration department at the same level.

Chapter VI Supplementary Provisions

Article 41 The National Bureau Verification Center shall organize the formulation of an annual inspection plan for testing institutions in accordance with the requirements of the National Bureau, conduct random inspections of testing institutions and inspect the supervision of testing institutions of relevant provincial bureaus. The inspection plan shall be submitted to the National Bureau for review and then organized for implementation.

Article 42 The key points and judgment principles for testing institution inspections shall be formulated by the National Bureau Verification Center. Provincial bureaus may formulate supervision and inspection work systems and requirements for testing institutions based on the actual situation within their administrative regions, clarify the division of responsibilities among departments, and strengthen the connection and coordination of relevant work. Article

43 The relevant technical institutions of the National Bureau shall initiate and implement drug clinical trial registration verification based on risks. If the drug registration verification finds relevant problems in the quality management system of the testing institution, they shall be evaluated and handled in accordance with these Measures.

Article 44 This Measures shall come into force on March 1, 2024.